

REMARKS

Rejection of claims 5, 7, 11 and 14-17 under 35 U.S.C. §102(b)

Claims 5, 7, 11 and 14-17 were rejected under 35 U.S.C. §102(b) as anticipated by Kawata et al. (US 4,258,179). Applicant respectfully traverses this rejection.

Claim 5 is drawn to a film-forming composition that comprises a film-forming base agent that is “a water-soluble cellulose base polymer” (emphasis added). In contrast Kawata describes a coating agent that includes a water-insoluble cellulose. For example, in the Abstract, the coating is said to include a “water-insoluble hydroxypropyl cellulose having 5-16% by weight of a hydroxyl-propoxy group.” The cellulose polymer is described in the same manner in column 1 at lines 1-24. Iwata describes a number of compositions that include such water-insoluble hydroxypropyl cellulose. Iwata makes a passing mention of water-soluble cellulose (coumn 1, lines 41-47) for use as a binding agent, but dismisses it as “unsuitable” and having a binding strength that is “insufficient”. Since the cellulose polymer of claim 1 is water-soluble, the composition of claim 1 cannot be anticipated by the compositions of Iwata, which include a water-insoluble cellulose polymer. Claims 7, 11 and 14-17 depend from claim 5 and cannot be anticipated by Iwata.

In view of the forgoing, Applicant respectfully requests that the rejection of claims 5, 7, 11 and 14-17 under 35 U.S.C. §102(b) be reconsidered and withdrawn

Rejection of claims 21 and 22 under 35 U.S.C. §102(b)

Claims 21 and 22 were rejected under 35 U.S.C. §102(b) as anticipated by Butler (US 3,049,433). Applicant respectfully traverses this rejection.

Claims 21 and 22 are drawn to formulations coated with a film-forming composition. Butler describes cellulose derivatives that are said to resist discoloration and can be used in, for example, paints (see column 1, lines 27-37). Butler never describes a formulation coated with the cellulose derivatives. Thus, no matter what the nature cellulose compositions described by Butler, this reference cannot anticipate either claim 21 or claim 22.

In view of the forgoing, Applicant respectfully requests that the rejection of claims 21 and 22 under 35 U.S.C. §102(b) be reconsidered and withdrawn.

Rejection of claim 18 under 35 U.S.C. §103

Claim 18 was rejected under 35 U.S.C. §103 as obvious in view of Kawata et al. (US 4,258,179) taken with Iwata et al. (WO 01/40182 A2). Applicant respectfully traverses this rejection.

Claim 18 is drawn to a capsule comprising the film-forming composition of claim 5. The Examiner argues that it would have been obvious to use the coating composition of Kawata in a capsule because Iwata teaches the “film coating of common dosage forms”

Even if one were to be motivated to use the cellulose coating of Kawata in capsule, one would not arrive at the capsule of claim 18 because the film-forming composition of claim 5 differs from the compositions of Kawata as described above in connection with the rejection of claims 5, 7, 11 and 14-17. For this reason, the cited references, no matter how combined, cannot render claim 18 obvious.

In view of the forgoing, Applicant respectfully requests that the rejection of claim 18 under 35 U.S.C. §103 be reconsidered and withdrawn.

Rejection of claim 23-26 under 35 U.S.C. §103

Claims 23-26 were rejected under 35 U.S.C. §103 as obvious in view of Butler (US 3,049,433) taken with Iwata et al. (WO 01/40182 A2). Applicant respectfully traverses this rejection.

The Examiner argues that it would have been obvious to make a cellulose film composition as described by Butler and “substitute it for the film coating composition that coats dosage forms such as tablets, granules and capsules, as taught by Iwata, and produce the instant invention.”

Butler teaches cellulose compositions that are used in water-based paints (see column 1, lines 27-29). The cellulose compositions are said to be more resistant to discoloration when exposed to high heat. The compositions were coated onto glass and dried at 221°F and then heated at 400°F for 20 minutes. In contrast, Iwata uses cellulose compositions in solid pharmaceutical formulations of a crystalline form of a specific drug. One skilled in the art of pharmaceutical formulation that was in need of a coating composition for a pharmaceutical

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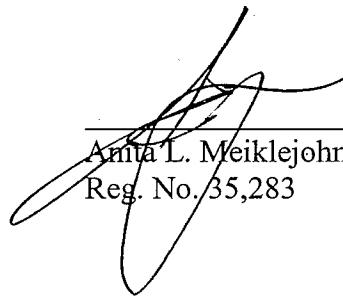
composition such as a tablet or capsule would not turn to a cellulose composition such as that described by Butler that designed for latex and water based paints and resistant to discoloration under high heat. First, the fields of endeavor are entirely different – paints and pharmaceuticals. Second, pharmaceuticals should not be exposed to heat due to the risk of breaking down the active ingredient. Butler is non-analogous prior art because it is neither in the same field of endeavor as the rejected claims and because it is not reasonably pertinent. *In re Clay* 966 F.2d 656 (Fed. Cir. 1992). Cellulose compositions for use in paints and cellulose compositions that resist discoloration at high temperatures are simply not relevant to pharmaceutical compositions such as those disclosed by Iwata.

In view of the forgoing, Applicant respectfully requests that the rejection of claims 22-26 under 35 U.S.C. §103 be reconsidered and withdrawn.

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Respectfully submitted,

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